K073134

510(K) SUMMARY FOR THE INT/DL40i MICRO COMPUTER CONTROL FOR POWER WHEELCHAIRS

This summary of 510(k) safety and effectiveness information is being supplied in accordance with the requirements of the SMDA of 1990 and 21 CFR 807.92

The assigned 510(k) number is _____.

Date: November 5, 2007

Submitted by: Invacare Corporation
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NOV 1 6 2007

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Contact Person: Mr. Carroll Martin

Trade Name: INT/DL40i Micro Computer Control for Power Wheelchairs

Common Name: Power Wheelchair controller and Joystick

Classification Name: Wheelchair, powered per 21 CFR 890.3860

Legally Marketed Predicate Device(s): INT/DL40i Micro Computer Control for Power Wheelchairs; K950724, August 7, 1995

Device Description: The INT /DL40i controller is an electronic microcomputer based motor control device for power wheelchairs intended to activate and control the wheelchair motion. It also provides the means for selecting, adjusting and programming the type of wheelchair operation parameters and performance characteristics to meet the particular control needs of the wheelchair user.

The INT/DL40i controller consists of a single module that includes both the joystick and the motor controller. It has two drive modes and twelve performance adjustment settings in its program menu. Programming the controller requires the use of a separate programming device since it does not have "Through the Joystick Programming" (TTJP) capability. Also, the INT/DL40i controller does not include any additional motion control activation devices such as "Sip N Puff" or seat reclining.

Intended Use: The intended use of the Invacare INT /DL40i Controller is to activate and control powered wheelchair motion. Additionally, it provides a method of selecting the type of operational parameters which best suit the particular control needs of the wheelchair

Substantial Equivalence:

Features	The Modified Model INT/DL40i	Predicate Device Model INT/DL40i
510(k) Number	**TBD**	**K950724**
Date Cleared	**TBD**	**08/07/1995**
Intended Use	To activate and control powered wheelchair motion. Additionally, it provides a method of selecting the type of operational parameters which best suit the particular control needs of the wheelchair user.	To activate and control powered wheelchair motion. Additionally, it provides a method of selecting the type of operational parameters which best suit the particular control needs of the wheelchair user.
Electronics	Digital Based	Digital Based
Drive Control	Microprocessor	Microprocessor
PC Boards	Surface and Through Hole Mounted	Surface and Through Hole Mounted
Drive Modes	2	1
Controller Module	Integrated with Joystick	Integrated with Joystick
Sip 'N" Puff Module Option	No	No
ECU Module Option	No	No
Recliner Module Option	No	No
RIM Control Option	No	No
Remote Programmer Option	Yes	Yes
LCD Joystick Option	No	No
TTJP Capability	No	No
Performance Adjustments	12	6
Enclosures	Pressure Die Cast Aluminum- Bottom Injection Molded Polymer - Top	Pressure Die Cast Aluminum
Manufacturer	Dynamic Controls, Ltd., Christchurch, New Zealand	Dynamic Controls, Ltd., Christchurch, New Zealand

As the chart above shows, the modified INT /DL40i Controller is substantially equivalent to the INT /DL40i Controller, cleared on August 7, 1995 under 510(K) Accession Number K950724. The modifications subject to this Special 510(k) consists only of testing to allow the use of the controller on a different model of Invacare's Pronto wheelchairs, the M41.

The intended use of activating and controlling powered wheelchair motion and providing a method of selecting the type of operational parameters which best suit the particular control needs of the wheelchair user remains the same.

Standard or Agency	**Title**
ANSI/RESNA WC/Vols. 1&2, 1998	
Section 1	Determination of Static Stability
Section 2	Determination of Dynamic Stability of Electric Wheelchairs
Section 3	Test Methods and Requirements for the Effectiveness of Braking
Section 4	Determination of Energy Consumption of Electric Wheelchairs and Scooters – Theoretical Range
Section 5	Determination of Overall Dimensions, Mass and Turning Space
Section 6	Determination of Maximum Speed, Acceleration and Retardation of Electric Wheelchairs
Section 7	Method of Measurement of Seating and Wheel Dimensions
Section 8	Requirements and Test Methods for Static, Impact and Fatigue Strengths
Section 9	Climatic Tests for Electric Wheelchairs – Requirements and Test Methods
Section 10	Determination of Obstacle Climbing Ability of Electric Wheelchairs
Section 14	Power and Control Systems for Electric Wheelchairs
Section 21	Requirements and Test Methods for Electromagnetic Compatibility

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CISPR 11	Industrial, Scientific and Medical (ISM) Radio Frequency Equipment-Electromagnetic Disturbance Characteristics-Limits and Methods of Measurement

Performance Data: The performance data found in this submission shows that the INT /DL40i Controller performs as intended and in a manner that is substantially equivalent to the predicate device.

Conclusion: The data presented in this submission shows that the INT /DL40i Controller performs as intended and in a manner that is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2007

Invacare Corporation
% Mr. Carroll Martin
One Invacare Way
Elyria, OH 44035-4190

Re: K073134
Trade/Device Name: INT/DL40i Micro Computer Control for Power Wheelchairs
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: November 5, 2007
Received: November 7, 2007

Dear Mr. Martin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Invacare INT /DL40i Controller

Indications for Use: The intended use of the Invacare INT /DL40i Controller is to activate and control powered wheelchair motion. Additionally, it provides a method of selecting the type of operational parameters which best suit the particular control needs of the wheelchair user.

Prescription Use ✔ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of ~~CDRH~~, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number k073134